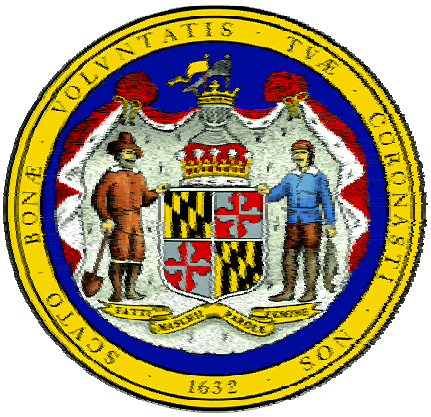
An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Home Health Services

Summary and Analysis of Public Comments And Staff Recommendation



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Summary and Analysis of Public Comments and Staff Recommendations

An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Home Health Agency Services

I. Introduction

The Maryland Heath Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Home Health Services*, was developed as one in a series of working papers examining major policy issues of the Certificate of Need process, as required by House Bill 995 (1999). The paper provides the basis for public comment on a series of potential alternative regulation strategies:

Option 1:	Maintain Existing Certificate of Need Program Regulation
Option 2:	Expanded CON Program Regulation (Require CON or Exemption from CON to Close an Existing Program.)
Option3:	Expanded CON Program Regulation (Require RSAs to obtain CON Approval)
Option 4:	Retain CON Review, but Project Need and Consider Applications on a Regional, not Jurisdictional Basis
Option 5:	Partial Deregulation (Regulate Only Sole/Two-Provider Jurisdictions)
Option 6:	Deregulation from CON, with Creation of a Data Collection and Reporting Model to Assure Quality (Consumer Report Card, or Provider Feedback Reports)
Option 7:	Deregulation from CON, with expansion of the Ombudsman Role to include Community-Based Services.
Option 8:	Deregulation from CON, With Expanded Licensure Standards and Oversight
Option 9:	Deregulation from CON Review, with or without Moratorium on New Agencies or Expansion of Service Area

The objective of this working paper is to provide information to the Commission on whether changes are needed with respect to CON regulation of home health agency services. The working paper was released for public comment at the September 15, 2000 meeting of the Maryland Health Care Commission. As of the date of this paper, eleven (11) written comments have been received. Those public comments, submitted by the following organizations, are summarized in Part II. Staff analysis of the public comments is provided in Part III. A staff recommendation is provided in Part IV. The organizations providing public comment include:

- Carroll County General Hospital
- Carroll Home Care
- Elizabeth Cooney Personnel Agency
- Johns Hopkins Medicine

- GBMC Healthcare, Inc.
- Howard County Board of Health
- Maryland-National Capital Homecare Association
- MedStar Health
- The Association of Maryland Hospitals & Health Systems (MHA)
- The Nurse Bank of Maryland, Inc.
- Tri-Cities Nurses Registry & Helpmates, Inc.

II. Summary of Public Comments[1]

Carroll County General Hospital (CCGH) is the only hospital in Carroll County**.** Home health care is a component of the continuum of care that is provided to its patients. CCGH strongly supports Option 1, maintaining the existing Certificate of Need program regulation. CCGH's interest in the regulation of home health agency services is to ensure the continued availability of quality, community-based home health agency services to its patients. CCGH believes the CON requirement is the only way to ensure that a new provider does not enter the market unless (1) there is a need for a new provider; (2) the provider satisfied a variety of criteria designed to ensure that its services will be high quality, non-discriminatory, financially accessible, cost effective; (3) the provider has the necessary commitments and ties to the community in which it proposes to provide services; and (4) the provider will not have an adverse effect on existing providers. CCGH believes that new home health agencies that do not meet these requirements will have a negative impact on the health care system.

The removal of the restriction on market entry, according to CCGH, raises the possibility that supply will increase, which in turn will increase the costs to existing providers with ties to the community, potentially driving them out of the market in which reimbursement is fixed prospectively. If the new providers, who may be national for-profit companies with little or no commitment to the community, later decide to leave, the community will be left with unmet need. CCGH further states that it is not aware of any evidence to suggest that the current system is in need of change. There is no unmet need for home health agency services anywhere in the state, and the hospital maintains there is no need to "open the floodgates" in Maryland by deregulating market entry and experiencing the kind of excess and resultant abuses that other states have experienced.

Carroll Home Care, Inc. (CHC) is a free-standing home health agency affiliated with Carroll County General Hospital. CHC supports Option1, because the CON requirement ensures that the new home health agency cannot enter a community unless there is a need, and requires that the new agency must meet the same criteria related to quality, financial viability, cost, access, and community ties that existing providers were required to meet. CHC states that, in the absence of need, establishment of a new home health agency will a negative impact on the health care system in the community, because it would result in competition between more players chasing limited staff and a constant

[1] A complete set of the written copies received on the Home Health Agency Services Working Paper may be obtained by contacting the Division of Health Resources at (410) 764-3232

number of patients for a pre-determined level of reimbursement. CHC, like most other health care providers, is having difficulties in finding and retaining qualified nurses and other staff. Accordingly, new home health agencies in Carroll County would only exacerbate this problem and increase CHC's employee costs.

CHC is also concerned about making any changes in the regulation of home health agencies while the industry is undergoing changes in reimbursement as well as in data collection and reporting, resulting from the implementation of 1997 Balanced Budget Act and OASIS (the Outcome and Assessment Information Set) required by the Act. CHC believes that changes to the CON requirement should not be considered until the full impact of these changes has been absorbed and analyzed. CHC feels that the CON requirement has protected Maryland from the excesses and abuses experienced in states without a CON requirement during the last decade. According to CHC, to change this process at this time is not in the public interest.

Elizabeth Cooney Personnel Agency, Inc. (The Cooney Agency) is a nursing referral agency. The Cooney Agency supports Option 7, the expansion of the Department of Aging's Long Term Care Ombudsman program, although it recommends that such a program be administered through the Office of Health Care Quality. The Agency also supported Option 8, deregulation from CON with expanded licensure standards and oversight, which allow for the existence of nurse registries. The Cooney Agency's primary concern is that the consumer of home health agency services deserves as many options as possible; it believes that the market will "naturally thin itself out." It does not believe in any form of regulation or expanded regulation of general home care services, because there would not be an access problem, even if some agencies were to close. The Agency also states that any new regulatory framework should allow for the "nurse referral agencies" to continue, with standards and oversight as appropriate to allow them to operate as independent contractors. Consequently, the Cooney Agency supports the Community-Based Health Agency legislation (discussed in the working paper on home health agency issues) with amendments to address its position that nurse registries should remain as a separate entity.

GBMC Healthcare, Inc. (GBMC) provides home health agency services through its subsidiary, Diversified Health Enterprises. GBMC supports Option 9, the deregulation of home health agency services from CON review, maintaining that "it is now time to eliminate the need for CON to initiate home health care programs." Existing direct oversight and regulation of home care services is exercised on the federal level by HCFA, the federal Office of the Inspector General, and through State licensure by the Office of Health Care Quality; other avenues of authority over home health agencies include the Health Professional Boards and Commissions, the Maryland Department of Aging, the Office of the Attorney General, and the Maryland Health Care Commission. Consequently, GBMC maintains that there are sufficient checks in place to ensure the quality of care provided in home care programs.

Howard County Board of Health supports Option 8, the deregulation of home health and hospice agency services, with expanded licensure standards and oversight. The Board believes that this option will result in a decrease of the capital necessary to

begin a project but will still maintain oversight of licensure and quality. The Board of Health believes strict standards of quality and their enforcement are important for home health and hospice agencies.

Johns Hopkins Medicine (Hopkins) supports Option 1, maintaining existing CON regulation for both home health and hospice agencies. Hopkins feels that home health care is an integral component of the continuum of care provided to patients who require ongoing support outside of the acute hospital setting, and believes that maintaining CON regulation is the best method of maintaining control over the number of agencies operating in the State of Maryland, and consequently over the quality of care provided by those agencies. Providing compassionate, responsive, high quality care requires significant investment in infrastructure to meet the requirements of regulatory and government agencies for providing and documenting care and for delivering equipment in the home. Proliferation of home care agencies, without demonstrated need, could negatively impact the ability of the existing agencies to retain sufficient market share to remain viable. Hopkins also recommends that, where additional services are needed, existing CON holders have priority for approval, and that Residential Service Agencies (RSAs) come under expanded licensure standards and oversight, making these agencies accountable for the credentialing and quality control for all care providers who enter the home of these vulnerable patients.

Maryland-National Capital Homecare Association (MNCHA) represents over 80 home health, home medical equipment, hospice, nurse registries, and infusion providers in Maryland and the District of Columbia. No consensus exists among MNCHA's membership on any one particular option for future government oversight of home health agencies. Its members have been closely divided on the issue of maintaining CON regulation, and oppose expanded CON regulation for closures, out of the belief that all jurisdictions would be adequately served by home health agencies even if some agencies were to close.

On the option of extending CON regulation to RSAs, MNCHA believes that there should be an even regulatory playing field for all home health providers who offer services in Maryland, although its members disagree on how these services should be regulated, and by whom. MNCHA expressed support for the Community-Based Health Agency legislation of 1999, and felt that creation of this comprehensive licensure category would help level the playing field for all agencies, without expanding CON. The organization had no preference on the question of regional versus jurisdictional need projection, but opposed limiting CON regulation to sole- or two-provider jurisdictions, because that practice would limit consumer choice in those areas.

MNCHA does not support additional data collection, citing the existing data requirements imposed on home health agency providers by HCFA (OASIS), JCAHO (ORYX), as well as the Commission's own annual survey, required as a condition of Maryland licensure. Not only do home health agencies already respond to significant mandates for data collection and submission, but as of October 1, 2000, providers are adjusting to the full implementation of Medicare's prospective payment reimbursement system. Given those considerable changes to the existing regulatory oversight of home

health agencies, the Association asks that the Commission allow the industry to "stabilize" prior to any additional requirements. On the option of expanding the role of the Department of Aging's Long Term Care Ombudsman program, MNCHA expressed a preference that this function be expanded through the Office of Health Care Quality rather than the county-level Offices on Aging.

MedStar Health Visiting Nurse Association (MedStar) is a not-for-profit home health care agency now comprised of the former Medlantic and Helix home care agencies. MedStar Health has expressed support for the CON model of regulation, "especially for specialized health care services because of its benefits in ensuring access to quality and cost effective services."[2] One reason MedStar and its VNA affiliate support continued CON regulation of both home health and hospice agencies is that "home health patients are particularly at risk of victimization" and potential fraud, and the current CON model prevents "a great deal of unscrupulous dealings." Further, the CON model assists in assuring that providers possess the essential non-financial resources for care delivery, before they begin operation. Consequently, MedStar believes that CON regulation protects not only the consumer, but also existing providers, "guaranteeing that there is quality in the start-up of a new program, there is viability in a new program, and that there is sufficient need in the jurisdiction."

The Association of Maryland Hospitals and Health Systems (MHA) supports Option 9-total deregulation of home health services from Certificate of Need Program Regulation without a moratorium on new or expanded services. MHA believes deregulation is appropriate for several reasons. First, of the universe of providers that provide home health agency services, only home health (and hospice) are regulated through CON; therefore, market entry cannot be effectively regulated. Secondly, the free market and the 1997 BBA reductions are doing an efficient job of controlling market entry due to increased financial risks. Thirdly, additional checks are already in place to ensure the quality of care provided in home health programs such as criminal background checks. Finally, startup of home health programs requires minimal capital investment and has little cost implication for the system, unlike CON applications which are not without considerable expense.

The Nurse Bank of Maryland, Inc., a nurse registry, supported maintaining existing CON regulations for home health agencies, but opposed regulation of nurse registries in any form[3].

Tri-Cities Nurses Registry & Helpmates, Inc., another nurse registry, believes that nurse registries should not be included in the debate about home health agencies and CON regulation; this was not an option proposed in the working paper. Like the Cooney Agency, Tri-Cities opposes any increased government oversight and regulation of nurse registries.

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[2] Letter to John M. Colmers from John L. Green, Executive Vice President, Corporate Services, MedStar Health, October 17, 2000.

[3] The staff working paper on home health agency services did not include an option for regulatory change that would impose CON review on either nurse registries or nursing staff agencies.

III. Staff Analysis of Public Comments

A. Option 1: Maintain Existing CON Regulation

Carroll County General Hospital, and its affiliate Carroll Home Care support maintaining the existing Certificate of Need program because it requires that any new provider seeking to enter the market to meet the same criteria related to clinical quality, provision of charity care, and cost-effectiveness as existing home health agencies, and because the CON approval of additional agencies may only be considered if new service capacity is needed, thereby minimizing the potential negative impact on existing agencies. Another concern the two Carroll County health care providers express is the likelihood that, without the CON requirement, more providers without close ties to the community will compete with locally-based agencies, potentially driving them out of the market. More home health agencies mean more competition for nursing and other agency staff during a serious shortage of health professionals, while the number of patients remains relatively stable, and the advent of PPS may reduce overall reimbursement levels.

Two of the largest health systems operating in Maryland, Johns Hopkins Medicine and MedStar Health, both support continued CON for home health agencies. **Johns Hopkins Medicine** supports maintaining CON as the best way to link any increase in the number of home health agencies to demonstrated need, and to subject new agencies to the same requirements enforcing access, cost-effectiveness, and quality of care as existing agencies. Maintaining CON oversight of this sector of health care helps ensure that existing agencies remain financially strong and clinically sound, and prevent the diffusion of the market among smaller, weaker agencies. **MedStar Health** also supports maintaining the existing CON oversight of home health agency services as a means of protecting the consumer, through its threshold review for the "non-financial resources" needed to operate a viable program, and also protecting the viability and strength of existing providers.

B. Option 2: Expanded CON Program Regulation (Require CON or Exemption from CON to Close Existing Programs

No commenter supported this option. While not opposed to some government oversight of facility closing, MedStar does not believe that the process should be "more burdensome or labor intensive." Ultimately, those who commented on the option of requiring CON approval to close an existing home health agency believe that the supply of home health agencies – and the fact that an agency's capacity may be expanded by the addition of more staff, who might be hired after another agency closes – guarantee that existing agencies can compensate for any that close. Both MedStar and MNCHA support the current Commission practice of requiring a home health agency that intends to close to notify the Commission, as it must notify the Office of Health Care Quality.

C. Option 3: Expand CON Regulation to Require CON Approval for RSAs

Johns Hopkins Medicine supports expanded licensure standards and oversight for residential service agencies, making these agencies accountable for all care providers who enter the homes under their auspices. **MedStar** opposes extending the CON review requirement to RSAs, because traditionally these agencies perform non-specialized services. Although **MNCHA** does not take a position on extending CON review to RSAs, it does support a level regulatory playing field for all home health care providers in Maryland, including RSAs. **The Cooney Agency** opposes any extension of CON regulation, as potentially expanding further to include nursing staff agencies, not currently covered by either CON or licensure by OHCQ. **The Cooney Agency** joins MNCHA in its support of the approach taken by the 1999 Community Based Health Agency legislation, provided that nurse referral agencies are excluded. **The Nurse Bank of Md., Inc.** opposes CON regulation of RSAs as well as nurse registries, believing that increased regulation would contribute to the shortage of health care workers. It recommends that "the CON process should be dropped," and only home care agencies reimbursed by Medicare and Medicaid should be subject to any level of regulation as health care providers.

D. Option 4: Retain CON; Regulate by Region, Not Jurisdiction

No commenter supported this option**.** The nurse registry-nursing staff agency sector simply opposes CON regulation in general. **MedStar** opposed this option because home health is not a regional specialized service, "although it may be organized and managed to cover a wide geographical area," but instead identifies a local need and service area. MedStar is concerned that "there may be some difficulty in assuring the quality of care standard" if services are consolidated on a regional, rather than a jurisdictional basis. Staff observes that State licensure standards are consistent throughout Maryland, and home health agencies also adhere to national standards and reporting requirements imposed by HCFA. Many of Maryland's home health agencies provide services on a regional, even a multi-regional basis, but must conform to HCFA standards that set maximum travel times for nurses to patients' homes. Staff proposed this option both because a regional application could simplify the CON application process for home health agencies, and because of the potential administrative efficiencies for multi-county agencies with centralized main offices, but no commenter identified a problem warranting this solution.

E: Option 5: Require CON Only in Sole-Two Provider Jurisdictions

Similarly, no one supported this option. **MNCHA and the Cooney Agency** opposed this option because they believe it would restrict consumers' choice of home care providers, although MNCHA expressed concern about potential problems where there is only one provider serving a jurisdiction.

F: Option 6: Deregulation from CON; Create Data Reporting Model

Those organizations submitting public comment were united in opposition to this option, if it represented an *additional* data reporting and evaluation requirement, to a significantly more complex and detailed federal requirement imposed by the 1997 Balanced Budget Act, in OASIS. The home health agencies, and health systems operating home health agencies, unanimously entreated the Commission not to recommend imposing another data collection mandate or "report card," in addition to the Commission's annual survey already required by OHCQ as a condition of continued or renewed licensure. Because the home health industry is adjusting to far-reaching changes in data collection and reporting as a result of the implementation of the Balanced Budget Act, and because the clinical accuracy and completeness of these data will have a direct bearing on the agencies' future reimbursement under home health's newly-final Medicare PPS system, the existing agencies strongly opposed any additional data reporting. Staff's working paper noted concerns about the effect of the federal changes on the continued availability in all regions of a full range of home health services – specifically about the possibility of widespread agency closures, or cost-shifting to insured patients, as a result of HCFA's stringent new requirements. These concerns support the home health industry's request, articulated by MNCHA, that changes to the CON requirement not be considered until the full impact of these changes has been absorbed and analyzed, and the industry's situation becomes more stable.

G. Option 7: Expand Department of Aging's LTC Ombudsman Program

Several commenters supported this option in principle, although expressing the preference for a consumer-oriented program to operate on the county level by the Office of Health Care Quality. This option is not budget-neutral for the State Department of Aging, and would require significant interagency research and development work, so the option is not part of Staff's recommendation to the Commission.

H. Option 8: Deregulation from CON, with Expanded Licensure Standards and Oversight

From its belief that applying for CON review of home health agencies imposes a significant level of transactional cost and capital expenditure, the **Howard County Board of Health** supports deregulation of home health agencies from CON, with expanded licensure standards and oversight. In common with the other entities supporting deregulation from CON with enhanced licensure, Howard's Board of Health believes that "strict standards of quality and their enforcement" are more important for home health and hospice agencies than limiting market entry, where the public interest is concerned.

I. Option 9: Deregulation from CON, with or without Moratorium

Supporters of this option want deregulation from CON review, without any expansion or extension to other home care entities of State licensure. **GBMC**

Healthcare, Inc., for example, supports deregulation of home health agency services from CON review, citing the multiple State and federal agencies with existing authority over reimbursement, data collection and reporting, consumer protection, and general quality of care. The consensus among those favoring deregulation from CON with no enhancement of other agencies' authority is that, essentially, enough government oversight exists to guarantee that all Maryland residents will continue to have access to cost-appropriate and high quality home health care, regardless of who enters or leaves this marketplace.

Those entities opposing deregulation from CON clearly disagree that the existing framework of government oversight – with no CON requirement to impose threshold standards, including charity care and other commitments presently beyond the scope of either State licensure or HCFA certification – provides enough consumer protection, or fosters a system of strong, solvent providers. Several organizations, in commenting on this option, noted a continuing concern with the inconsistency and inequality with which licensure and other safeguards are applied to the variety of entities currently providing Marylanders some level of health care in their homes. No commenters registered any enthusiasm for the imposition of a moratorium, which both the Staff working paper and the AHPA report discuss as the approach taken by many states, whether or not they continue to require CON approval for home health agencies.

The Association of Maryland Hospitals and Health Systems supports deregulation of home health agency services from CON because only home health (and hospice) agencies, in the range of entities providing health care in the home, are regulated through CON, and therefore market entry cannot be effectively regulated. In addition, MHA argues that "the free market and the 1997 BBA reductions are doing an efficient job of controlling market entry due to increased financial risk"; that the "additional checks" in place to ensure the quality of care provided in home health programs are sufficient; and that start-up costs for home health programs require only a minimal capital investment and "their failures have little cost implication for the system." Since "CON applications, which have been routinely processed and approved in the past, are not without considerable expense," MHA argues that both home health and hospice agencies should not require CON review and approval.

The following table summarizes the public comments received on the regulatory options presented in the Staff working paper on home health agency services. An (S) indicating support and (O) indicates opposition; where the entity's position is neither clear or unequivocal support nor clear opposition, no position appears.

	REGULATE					*DEREGULATE*			
	Option 1	**Option 2**	**Option 3**	**Option 4**	**Option 5**	**Option 6**	**Option 7**	**Option 8**	**Option 9**
CCGH	**S**	--							O
CHC	**S**	--				O			
GBMC									**S**
Hopkins	**S**		(1)						
Howard								**S**	
Medstar	**S**	O	O	O					
MCNHA	--		--	--	O	O	(2)		
MHA									**S**
Cooney*	O	O	O	O	O	**S**/O	**S**	**S**	
Tri-Cities**	**S**								
Nurse Bank**	**S**		O						

*Nursing Staff Agency

**Nurse Registries

(1) Recommend expanded licensure standards and oversight for RSAs.

(2) Expand Ombudsman role through OHCQ.

IV. Staff Recommendation

Staff recommends that the Commission adopt a modified version of Option 8, recommending to the General Assembly the deregulation of home health agency services from Certificate of Need review, contingent upon the enactment of statutory authority for the Department's Office of Health Care Quality to reorganize and expand the scope of State licensure standards for all entities providing home health care. Staff further recommends that the effective date of the deregulation from CON review of home health agency services be delayed until eighteen months following the effective date of any regulations required to implement the statutory changes needed to modify State licensure standards for this service. This will help to ensure that the clinical and financial viability standards now enforced at the time of market entry as commitments and conditions incorporated in CON approvals are included in the expanded State licensure standards, and have been "road-tested" and amended, if necessary, to address any Commission concerns about the impact of the shift from CON to a combination of stronger State licensure and stringent federal data and outcome reporting.

Under this framework, the role of government oversight in home health care would shift from regulating market entry through CON, based on projected need for services, to reviewing would-be new providers, and applications for license renewal by existing providers, according to a broader set of State licensure rules and requirements. Home care providers seeking to become or remain the equivalent of today's home health agencies by obtaining Medicare certification in addition to licensure – would have to comply with HCFA's OASIS clinical and outcome data reporting requirements, and its new prospective payment system. This stronger licensing program would impose as a condition of initial and renewed licensure some of the standards reviewed for initial compliance in the current CON review process. A commitment to provide an appropriate

level of charity care and care for Medicaid and gray area populations, linkages to other community health care providers, ready access to respite care, an active effort at communication and public information – all of these are CON review standards that should be incorporated into a more comprehensive program of State licensure.

The rigorous and extensive OASIS data reporting requirements imposed by the 1997 BBA and the new PPS (in effect as of October 1, 2000 following an interim, transitional stage) have already affected the supply of home health agencies, with no change in what or how the Commission regulates home health agency services. Between January 1, 1997 and May 1, 2000, a total of 25 home health agencies closed (15 private and 10 operated by local health departments), and 20 more merged with other agencies. Fourteen previously-approved CONs to establish home health agencies were relinquished during FY 2000, and another seven CONs were relinquished during the previous fiscal year. Both existing agencies and those attempting to start operation have felt the BBA's impact: these more stringent federal conditions alone have proven an effective barrier to market entry (and survival) in Maryland.

Staff believes that the combined effect of a more comprehensive State licensure program with the significantly increased level of federal oversight mandated by the 1997 BBA can assume the cost and quality functions of the CON review requirement – with several important caveats and conditions. CON review performs in effect a threshold evaluation of an applicant's clinical capabilities, financial viability, and administrative practices, and requires commitments to public information and to charity care before the Commission acts to grant CON approval.

If the General Assembly grants to the Department the necessary authority to create the Community-Based Health Agency licensure category, these elements (and a data reporting requirement to verify compliance) will have to be incorporated into the implementing regulations, and made a condition both of first licensure, and of license renewal for any existing home care agency. Those CBHAs seeking Medicare certification will, of course, have to comply with the additional HCFA requirements, and the Commission would continue to administer the annual survey now used by the Department as the annual report required of home health agencies.

That the Commission continues its role in conducting and analyzing the annual survey of all home health agencies (whether or not this data collection is extended through CBHA licensure to all providers of health care in the home or community) is of crucial importance. In that way, the impact of both the increased HCFA requirements as well as an expanded, comprehensive State licensure program may be monitored and evaluated, so that their combined effect on Marylanders' continued access to home health care of high quality can be measured, and understood.